

### **REMARKS**

Favorable reconsideration and allowance of the claims of the present application are respectfully requested.

In the present Office Action, the title of the present application has been objected to because the original title is allegedly not descriptive of the present claims. Accordingly, the Examiner has requested that the applicants provide a new title that is descriptive of the invention presently claimed. In response to the Examiner's request for a new title, applicants have amended the title of the present application to read as follows: WATER-BASED EMULSIFIER WAX GELS INCLUDING FREE SPHINGOID BASES AND OIL-IN-WATER EMULSIONS INCLUDING THE SAME. This new title is consistent with the title proposed by the Examiner and it is descriptive of the claimed invention. Reconsideration and withdrawal of the objection to the title of the present application are respectfully requested.

In addition to the above, the Examiner has noted other informalities that exist in the originally filed application. Applicants have addressed each of the Examiner's objections by amending portions of the application in which the alleged informalities were located.

In addition to those amendments to the specification, applicants have also changed paragraphs [0039] and [0042] in the manner indicated above. Specifically, the indication of comparative example 2 and reference example 3 were switched. Applicants note that this switching of example nomenclature does not introduce any new matter into the application. Rather, it fixes an apparent error in the examples where the comparative example 2 and reference example 3 were mistakenly labeled. Applicants note that the

comparative examples add the lipid to the oil phase whereas the reference example adds the lipid to a water phase.

Since the above amendments to the specification do not introduce any new matter into the specification of the instant application, entry thereof is respectfully requested.

Claims 7-8 are objected to because of the specific informalities mentioned under item 5 of the present Office Action. Claim 8 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter that the applicants regard as their invention.

In response to the objection to Claim 7, applicants have removed the extra 'period' from the claim. Insofar as the objection and indefinite rejection to Claim 8 are concerned, applicants have cancelled Claim 8 in this response.

Applicants respectfully submit that the above amendments to Claims 7 and 8 obviate the informal objections and indefinite rejection mentioned above. As such, the objection to Claims 7 and 8 and the indefiniteness rejection to Claim 8 can and should be withdrawn.

In addition to the above amendments to Claims 7 and 8, applicants have also amended Claim 1 to positively recite the amounts of each component present in the claimed water-based emulsifier wax gel and to specify the types of lipid and emulsifier used as components a and c, respectively. Specifically, Claim 1 has been amended to positively recite a water-based emulsifier wax gel including

- a) *1 to 4 % by weight of a skin-identical free sphingoid base,*
- b) *0.5 to 6.0 % by weight of at least one nonionic or anionic emulsifier,*

c) 1 to 8 % by weight of at least one wax-like consistency-imparting agent,  
and

d) 80 to 98 % by weight water.

Applicants submit that the above amendment to Claim 1 is supported throughout the present application and in the original claims. For example, see original Claims 3, 5, 6, 9, 11 and 12. Since the subject matter from those dependent claims was incorporated into independent Claim 1, applicants have cancelled Claims 2, 3, 5, 6, 9, 11 and 12 in this response.

In addition to the foregoing amendments, applicants have also amended independent Claims 16 and 18 to positively recite that the lipid is a *skin-identical free sphingoid base*. Applicants submit that these amendments to Claims 16 and 18 are supported by the instant application. See in particular, original Claim 3, or paragraph [0009].

Applicants have also added new Claim 20 which is supported by paragraph [0008] of the originally filed application.

Since none of the above amendments to the claims introduces new matter into the application, entry thereof is respectfully requested.

Claims 1-7 and 9-19 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent Application Publication No. 2002/0010215 to Shiroyama et al. ("Shiroyama et al."). Claim 8 stands rejected under 35 U.S.C. § 103 as allegedly unpatentable over the combined disclosures of Shiroyama et al. and U.S. Patent No. 6,362,142 to Weber et al. ("Weber et al.").

Concerning the § 102(b) rejection, it is axiomatic that anticipation under § 102 requires that the prior art reference disclose each and every element of the claim to which it is applied. In re King, 801 F.2d, 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1996). Thus, there must be no differences between the subject matter of the claim and the disclosure of the prior art reference. Stated another way, the reference must contain within its four corners adequate direction to practice the invention as claimed. The corollary of the rule is equally applicable: Absence from the applied reference of any claimed element negates anticipation. Kloster Speedsteel AB v. Crucible Inc., 793 F.2d 1565, 1571, 230 USPQ 81, 84 (Fed. Cir. 1986).

Applicants submit that the claims of the present application are not anticipated by the disclosure of Shiroyama et al. since the applied reference does not disclose applicants' claimed water-based emulsifier wax gel, as recited in Claim 1, process for preparing the same, as recited in Claim 16, oil-in-water emulsion, as recited in Claim 18, or process of making the oil-in-water emulsion, as recited in Claim 20. Applicants observe that in each of these claims at least a skin-identical free sphingoid base is employed in conjunction with the other components recited therein.

Shiroyama et al. disclose a clear aqueous ceramide composition with comprises 1 to 5 %, by weight, of a ceramide as recited by formula (I). Applicants observe that the prior art disclosure does not disclose the use of a skin-identical free sphingoid base as a replacement for ceramide in the disclosed aqueous compositions. Applicants further observe that in the prior art section of Shiroyama et al. it is disclosed in paragraph [0004] that a phytosphingosine-based ceramide (i.e., a ceramide made using a phytosphingosine as a building block) is mentioned in the context of a prior art composition which is free of

water. In addition to not containing water, Shiroyama et al does not disclose free sphingoid bases. Instead, ceramides are disclosed and illustrated in the prior art reference.

Applicants note that ceramides, such as disclosed in Shiroyama et al., are *fatty acid amides* of free sphingoid bases such as phytosphingosine, sphingosine and sphinganine. Chemically, ceramides and free sphingoid bases are very different, the latter being primary amines. It is the free amine group, which makes sphingoid bases such as phytosphingosine even more difficult to formulate as compared to ceramides. Whereas both ceramides and free sphingoid bases require high temperatures to get melted in the oil phase, it is only the sphingoid bases which disturb the emulsion formation process resulting in either inhomogenous or instable formulations. In contrast, once ceramides are melted in the oil phase, the emulsion forms easily and exhibits good long-term stability.

The foregoing remarks clearly demonstrate that the applied reference does not teach each and every aspect of the claimed invention, as required by King and Kloster Speedsteel; therefore the claims of the present application are not anticipated by the disclosure of Shiroyama et al. Applicants respectfully submit that the instant § 102 rejection has been obviated and withdrawal thereof is respectfully requested.

With respect to the § 103 rejection, applicants submit that the claims of the present invention are not rendered unpatentable by the disclosures of Shiroyama et al. in view of Weber et al., since none of the applied references teach or suggest applicants' claimed water-based emulsifier wax gel which includes, among other components, a skin-identical free sphingoid base and water.

The principle-applied reference, e.g., Shiroyama et al., spurring the obviousness rejection, is defective based on the remarks made above. Thus, the remarks made in conjugation with the anticipation rejection are incorporated herein by reference. To reiterate, Shiroyama et al. do not teach or suggest a water-based emulsifier wax gel, which includes, among other components, a skin-identical free sphingoid base and water. Shiroyama et al. disclose a clear aqueous composition that includes a ceramide, not the claimed skin-identical free sphingoid base.

Weber et al. do not alleviate the above defects in Shiroyama et al. since the applied secondary reference does not teach or suggest a water-based emulsifier wax gel which includes, among other components, a skin-identical free sphingoid base and water. Weber et al. provide a surface-active composition useful for cleaning various types of substrates such as articles of clothing, various types of hard surfaces, as well as, human hair and skin, the composition containing: (a) an esterquat; (b) a chitosan and/or chitosan derivative; and (c) a protein hydrolyzate. Applicants observe that in Col. 8, lines 10-17, there is mentioned other optional components that can be used in the composition disclosed in Weber et al. Included within the optional components are biogenic agents, in which ceramides, and pseudoceramides are mentioned at Col. 10, line 48. Weber et al. do not list the claimed skin-identical free sphingoid base, as one of the essential or optional components in their composition.

As such, the combined disclosures of Shiroyama et al. and Weber et al. do not render the claimed water-based emulsifier wax gel obvious.

The § 103 rejection also fails because there is no motivation in the applied references which suggest modifying the disclosed compositions to include the various

elements recited in the claims of the present invention. Thus, there is no motivation provided in the applied references, or otherwise of record, to make the modification mentioned above. "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." In re Vaeck, 947 F.2d, 488, 493, 20 USPQ 2d. 1438, 1442 (Fed.Cir. 1991).

The rejection under 35 U.S.C. § 103 has been obviated; therefore reconsideration and withdrawal thereof is respectfully requested.

Thus, in view of the foregoing amendments and remarks, it is firmly believed that the present case is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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